The Role of Law and Ethics in Recent Preparedness and Response for Vaccine-Preventable Illness

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This is the author's manuscript of the work published in final edited form as:

Silverman, R. D. (2020). The Role of Law and Ethics in Recent Preparedness and Response for Vaccine-Preventable Illness. *Public Health Reports*. https://doi.org/10.1177/0033354920949532

The Role of Law and Ethics in Recent Preparedness and Response for Vaccine-Preventable Illness

In 1999, the Centers for Disease Control and Prevention listed vaccination among the United States' leading public health achievements of the 20th Century.[1,2] Critical to this success were effective implementation and enforcement of state and local policies associated with school and daycare entry and infectious disease control.[3]

Twenty years later, the World Health Organization listed vaccine hesitancy – "the reluctance or refusal to vaccinate despite the availability of vaccines" – as one of the greatest global health threats.[4] Rising vaccine hesitancy in the US and abroad has contributed to high-profile outbreaks of vaccine-preventable illnesses. In 2019, the US reported a 27-year high in measles cases, coming within days of losing its endemic measles-free status.[5] Furthermore, state and local public health authority efforts to draw upon or strengthen public health laws to address preventable infectious disease outbreaks have been met by statehouse and courthouse challenges.

Most, but not all, of these challenges to local response efforts ultimately have been decided in ways reinforcing and deferring to foundational public health legal and ethical principles. A review of recent vaccine-related agency, legislature and court activity using these principles can help assess the scope, limits, and vulnerabilities of U.S. public health agencies' authority to protect the public from vaccine-preventable illnesses, and to address infectious disease threats like SARS-CoV-2, for which there are no current vaccines or treatments. As discussed further below, and seen in most states' COVID-19 response efforts, such a review also can demonstrate the importance of public health agencies and experts remaining diligent in efforts to educate and collaborate with their local political leadership.

Police Power, *Parens Patriae*, and Organized Society

Under the U.S. Constitution, the state, through exercise of its police power, holds the primary authority to protect the community's health, welfare, and safety. In its 1905 *Jacobson v. Massachusetts* decision,[6]

upholding a local health department's requirement that a local pastor subject himself either to receive a smallpox vaccination or pay a fine for refusing, the Supreme Court offered important guidance to states on exercising these powers and identified limits on individuals' Constitutionally-protected liberty rights when the state needs to protect the common good.

More than a century later, *Jacobson* principles continue to guide state and local use of public health power:

1. **Deference:** states, through their legislatures, possess broad authority to define what constitutes a public health concern, and courts are reticent to second-guess the wisdom of states' decisions about the scope and use of that authority.
2. **Delegation:** states may choose to endow expert state and/or local bodies (such as health departments) with its power to identify, track, and respond to public health threats.
3. **Necessity/Minimal Risk/Reasonableness:** because infringement on important personal rights (autonomy, parental authority, etc) may be unavoidable during an infectious disease outbreak, states must respond thoughtfully and proportionally to such threats. The means of response must keep individual health and safety risks as low as possible, and should only restrict Constitutionally-protected liberties when and to the extent they absolutely must to achieve the public health goal.[7]

Later Supreme Court decisions built upon *Jacobson*'s principles, finding states can establish vaccination-related school entry requirements that override a child's right to pursue private or public education,[8] or supersede an individual's right to practice her religious beliefs.[9] Furthermore, the state may restrict parental control of their children as part of its *parens patriae* responsibility to "guard the general interest in youth's wellbeing," even if parental actions are grounded in religious or deeply-held philosophical beliefs.[10] As the Supreme Court stated in *Prince v. Massachusetts*, "The right to practice

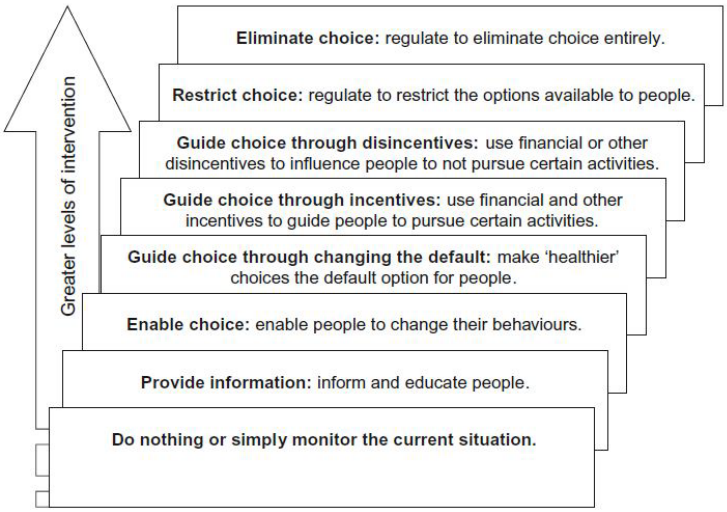
religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death."[11]

The *Jacobson* court states: if we were to hold individual rights and autonomy preeminent, even when facing significant public health threats, "organized society could not exist….Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy. Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others."[12] Ethicist Dan Beauchamp expands upon this stance, as he describes how application of police power authority "flows from a view of democracy that sees the essential task of government as protecting and promoting *both* private and group interests…. [I]t is left to the legislatures to determine which sets of interests predominate when conflicts arise."[13]

Bend-but-Don't-Break Interventions

In using its power, and to maintain trust in public health authorities, states should not merely be reasonable and transparent in their actions, but should "adopt the least restrictive alternative that will meet the public health goal."[14,15] At times of low risk (e.g. no current outbreaks in the area), our system preferences freedom. To address public health problems, states should take a stepwise, bend-but-don't-break approach to interventions. They should select first the feasible intervention that minimizes encroachment upon important individual freedoms, even if doing so might risk decreasing effectiveness, ratcheting up to more intrusive interventions only should that approach prove insufficient. The Nuffield Council on Bioethics *Intervention Ladder*[16] helpfully organizes public health actions from low to high coercion.

Figure 1: The Nuffield Council Intervention Ladder (2007)[xvi]



Ethically, the state should not look to the most coercive approaches as first steps in public health response. With infectious disease control, states must recognize that, to achieve a particular goal (e.g., eliminating endemic measles) they may not have to require either compulsion or 100% compliance with an intervention, even if that would more assuredly bring about the improvement. Instead, to build and maintain protective vaccination rates, public health agencies should first focus on maximizing vaccine access, implementing localized, community-engaged health communication and trust building initiatives, and improving immunization reporting and surveillance systems.

Social Distancing, Scope of Authority, and Declining Deference to Science

Several high-profile examples of local health department police power use occurred in 2019. A Kentucky Court of Appeals supported a local health department's bend-but-don't-break social distancing approach to address a chickenpox outbreak at a school where 80% of the students held religious exemptions to vaccination.[17] The department first prohibited unvaccinated students from participating in extracurricular activities during the outbreak, then, when the outbreak continued, prohibited such students from school attendance.[18] By upholding the health department's authority, the court reinforced several core concepts discussed above: (1) the state is not obligated to offer any kind of

exemption from vaccination as a condition of attending school; and (2) the state acted reasonably both in allowing students to attend school with a religious exemption when risks were low, while also retaining the authority to be more restrictive during outbreak response.

In March, a local New York court signaled a troubling turn away from the expert deference described in *Jacobson*. Rockland County, New York, a community with high numbers of religious exemptions, had been facing a months-long active measles outbreak.. Their latest outbreak mitigation attempt, declaring a 30-day public health emergency and barring *all* unvaccinated people from entering *any* place of public assembly, including schools, was challenged and thwarted by the local court. The judge noted the county exceeded its authority under local law, which only allowed 5 day emergency orders. The court also raised a worrisome second rationale for its decision. While the state Emergency Declaration law allowed such powers to be used when responding to "epidemics," neither the statute nor the emergency order offered a scientifically-grounded epidemic definition. Instead of deferring to the local authority's epidemic determination, the court decided that 166 measles cases in a population of more than 300,000 did not meet the term's "ordinary meaning." This case reminds us that documents, such as emergency orders, are not merely instruments through which governments exert their authority. Through the inclusion of statements such as, "Whereas the Centers for Disease Control and Prevention defines 'epidemic' as 'an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area,'"[19] they also can serve as opportunities to improve the public health literacy of the public and potentially reviewing courts.

In contrast, New York City, over the course of a nearly year-long measles outbreak centered largely in religious communities in Brooklyn, exemplified the step-wise, bend-but-don't-break approach infectious disease outbreak response approach. The city began with culturally-appropriate community education and increasing access to vaccination. They then supplemented this action with targeted social distancing measures, requiring that schools bar unvaccinated children from attendance during the active outbreak.

As some schools allowed unprotected children to continue attending, and the outbreak endured, the city increased their response's force: declaring a public health emergency, requiring unvaccinated individuals within certain Brooklyn zip codes be inoculated against measles or be deemed a public nuisance and forced to pay a $1000 fine.

Exemptions Eliminated, Loopholes Closed and Remaining, Deference Grudgingly Given

Arguably the most significant legal actions taken by states responding to outbreaks has been the elimination of exemption grounds from state school and daycare entry rules. After the 2015 Disneyland measles outbreak and a precipitous rise in families filing nonmedical exemptions, California became the third state to limit school and daycare vaccination exemptions to medical grounds. New York and Maine also eliminated nonmedical exemption grounds from their school and daycare entry laws this year. By contrast, following a significant measles outbreak, Washington eliminated personal/philosophical (but not religious) exemptions for the Measles-Mumps-Rubella vaccine,[20] raising interesting questions about whether there may be more nuanced ways to adhere to the "least restrictive" obligation via customizing state laws to the public protection needs related to individual infectious diseases.[21]

Since tightening their vaccination law, California saw a rapid rise in the number of medical exemptions submitted.[22] Following a contentious legislative session, the state passed a new law to increase the rigor of medical exemption oversight, empowering state public health authorities, under certain circumstances, to review and reject medical exemptions that do not adhere to expert guidelines. These standards, which will go into effect in 2021, demonstrate an attempt to find an appropriate balance between public health protection and individual rights, as they will be triggered when a community has a low vaccine uptake rate, when schools fail to report vaccination rates with the state, or in cases where a physician submits five or more medical exemption reports per year.

Few states have policies like California's offering public health authorities power to conduct substantive review and oversight of medical exemption writing, and it is unclear how many state medical licensure boards are willing to mount rigorous oversight campaigns against aberrant medical exemption writers.[23] Unlike California, Washington will continue to have a considerable public health protection loophole in its medical exemption submission process. In addition to not empowering the state to review and reject nonconforming medical exemption applications, Washington law allows an expanded range of health care providers, including naturopathic physicians, to complete the medical exemption qualification examinations and the medical exemption forms.

As the 2019-2020 school year approached, New York families filed legal challenges against their state's new vaccination requirements. In one decision, the judge expressed concern about the impact of the state's more restrictive law on many families, noting the relatively small percentage of the population that is exempting based on religious convictions, especially in comparison to the population that may be unprotected due to either poor access to care, vaccine failure, or waning protection due to the passage of time.[24] Nevertheless, in denying the family's request to stop the implementation of New York's new law, the judge ultimately felt bound by precedent, in line with *Jacobson*, deferring to the right of the state legislature to determine what equals a public health concern and the appropriate means by which to respond to such threats.

Conclusion

The whirlwind year of vaccine-related legal and political activity of 2019 offers insights into the policies states might establish should a safe and effective SARS-CoV-2 vaccine be developed. Given the overwhelming disruption caused by COVID-19 to the public's lives and the economy, there is likely to be great public interest in and demand for a vaccine. Therefore, it will be important to ensure that the vaccine be not only safe and effective, but also easily and broadly accessible at little or no cost to the

public. Robust, multi-cultural public education campaigns on the benefits, limitations, risks, and availability of the vaccine should precede and accompany the vaccine's distribution. High demand also may minimize the need to impose mandates, although mandates likely will be implemented in certain settings, such as those who work closely with immunocompromised or particularly vulnerable populations. Would states mandate a safe and effective SARS-CoV-2 vaccine for children? That will depend in part on what we learn of children's role in the disease's transmission, as well as the level and length of immunity granted by the vaccine. In the interim, it is certain we will continue to rely upon regular use of social distancing measures, coupled with improved testing, surveillance, and contact tracing, to control virus spread.

Finally, these infectious disease outbreaks highlight an important reminder to state and local public health officials: legislatures play a critical role indefining what constitutes a public health concern and the state's response. Those engaged in vaccine promotion efforts must clearly articulate, spread, and reinforce understanding of public health concepts, norms of solidarity and community connectedness, and public health's central role in supporting human flourishing. Public health authorities and experts need to consider part of their mission consistent engagement with and education of state and local officials, ensuring legislators understand the public health concerns arising in their communities, and that those charged with protecting the public's health retain the authority and have the resources to put into practice the evidence-based, science-informed interventions necessary to respond.

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